incorporates the proposed Examiner's Amendment sent to the attorney by facsimile on August 22 in a good faith attempt to place this application in condition for an immediate allowance.

In particular, the method now specifies that the vaccine composition, after a single administration, elicit protective immunity "for a duration of six months after the single administration" to conform to the proposed Examiner's Amendment and in accord with the unexpected results demonstrated in the working examples of the application. Surprisingly, the new one-dose vaccination of the unique formulation of the present invention evidences superior, long-term immunity against *M. hyopneumoniae* infection to a full six months after the single dose administration, which is a significant improvement in activity over the two-dose vaccination schedule of Suvaxyn® RespiFend® MH (that did not contain the claim-recited mixture of metabolizable oil and a polyoxyethylene-polyoxypropylene block copolymer) and the four months duration of immunity of Ingelvac® M. hyo (that contains an Impran® water-in-oil emulsion and is effective through one dose but only lasts 120 days) (see Examples 3 and 4 on pages 12-25 of the specification).

The guidelines of M.P.E.P. § 716.02(a) indicate that a *prima facie* case of obviousness can be rebutted by evidence of results that are unexpected and significant, *i.e.*, the results are greater than those that would have been expected from the art to an unobvious extent and the results are of a significant, practical advantage. In the case at hand, there is objective evidence that refutes *prima facie* obviousness. The working examples demonstrate that the method of the present invention provides beneficial and unexpected results over those seen in the art. By incorporating the advantageous long-acting property not possessed by the art formulations into the method claims, the amendment clearly overcomes the rejection based on the cited art.

Applicants respectfully ask the Examiner to consider and allow the scope of the amended Claim 10. Applicants have incorporated all of the proposed Examiner's amendment with the minor exception of not specifying the pig's age. The Examiner felt that the step of administration needed to be limited to administering the vaccine to the pig "at three weeks of age." Contrary to the Examiner's opinion, Applicants assert that since the pig's age is not critical to the practice of the present invention, the age restriction is not warranted under the circumstances. Plus, it will vary somewhat in actual practice; it is more a question of maturity than a precise age. Vaccination protocol will follow what is customary in the usage and trade.

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One of ordinary skill in the art will certainly appreciate when to vaccinate the piglets. While the specification illustrates vaccinating the piglets at three weeks old and it is desirable to administer the vaccine to the piglets at an early age to avoid *Mycoplasma hyopneumoniae* infection or disease, the exact timing of the administration of the vaccine is not always precisely at three weeks after birth.

Additionally, Applicants wish to inform the Examiner that the continuation-in-part Application No. 10/150,597 has been allowed by the U.S. Patent and Trademark Office on September 1, 2005. Of particular interest to the present case, the allowed method claims of the continuation-in-part, drawn to the method of using the vaccine combination composition against infection by *Mycoplasma hyopneumoniae* and a viral pathogen, which comprises the *Mycoplasma hyopneumoniae* bacterin, at least one viral antigen selected from the group consisting of swine influenza virus (SIV), porcine reproductive and respiratory syndrome virus (PRRSV), and porcine circovirus (PCV), an adjuvant mixture comprising an acrylic acid polymer and a mixture of a metabolizable oil and a polyoxyethylene-polyoxypropylene block copolymer and a pharmaceutically acceptable carrier, which vaccine composition after a single administration elicits protective immunity from *Mycoplasma hyopneumoniae*, do not specify when the combination formulation must be given to the pig. The allowance of these method claims without limitation as to age lends further support to Applicants' position that Claim 10 in the present application may be allowed without the restriction that the pigs be "at three weeks of age."

For all of the above reasons, Applicants believe that the age limitation "at three weeks of age" is not necessary in the instant Claim 10. It is hoped that the Examiner will reconsider and permit the method claims to issue without age restriction.

Most importantly, there is no description, suggestion or motivation taught in the combined art that single administration of the *Mycoplasma hyopneumoniae* bacterin when formulated according to the present invention could be successful at achieving effective immunity for six months. It is clear that there is no teaching to suggest or motivate a person of ordinary skill in the art to produce the vaccine described herein and to practice the claimed method. The ordinary practitioner simply would not arrive at the claimed invention without inventive effort.

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. In view of the amendment and the foregoing remarks, Applicants respectfully ask that the rejections of Claims 10-12 and 17 under 35 U.S.C. § 103(a) be withdrawn.

Turning to the double patenting rejection next, the Examiner has provisionally rejected Claims 10-12 and 14-17 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 14-18 of the co-pending Application No. 10/150,597. The Examiner states that the conflicting claims are not patentably distinct from each other because, in her opinion, the method claimed in the co-pending application is encompassed within the scope of the instant claims. Applicants respectfully disagree.

Notably, the method claims of Application No. 10/150,597 require the administration of a combination composition that includes at least one viral antigen. The inclusion of the viral antigen provides a patentable distinction in view of the restriction requirement in the continuation-in-part application. In that case, the examiner made a restriction wherein the first group comprised the claims drawn to a vaccine composition containing the *Mycoplasma hyopneumoniae* bacterin and a viral antigen. The second group comprised the claims drawn to a vaccine composition containing the *Mycoplasma hyopneumoniae* bacterin and a bacterial antigen. The examiner deemed the two inventions distinct for the following reasons: The products of the two groups are made up of different components, which are not required by each group; and the vaccines are biologically, chemically and structurally different. As an example, the examiner went on to say that the vaccine in the first group did not require at least one bacterial antigen in addition to the *Mycoplasma hyopneumoniae* bacterin and the viral antigen.

With respect to the present claims, the method does not require at least one viral antigen. Based on the rationale for the restriction requirement in Application No. 10/150,597, it seems reasonable to conclude that the presence of the viral antigen results in a vaccine that is biologically, chemically and structurally different from the vaccine recited in the instant Claims 10-12 and 14-17. Consequently, the provisional double patenting rejection cannot be sustained. Applicants respectfully ask that the provisional double patenting rejection be withdrawn.

The Examiner has also rejected Claim 10 under 35 U.S.C. § 112, first paragraph (new matter), because she apparently considers the limitation 'nasal' administration as new matter. To reply, Applicants have amended the claim language to provide "intranasal" administration

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in accord with the direct support found on page 6, line 2 of the specification. Since the amendment and the descriptive support in the specification will overcome the new matter rejection, it is respectfully asked that this rejection of Claim 10 be withdrawn.

The Examiner has further rejected Claims 10-12 and 14-17 under 35 U.S.C. § 112, second paragraph, for reasons given on page 14 of the Office action. Without comment as to the merits of this rejection but to advance prosecution towards an allowance, the claims have been rewritten for the better readability thereof. It is noted that support for the revision to polyoxyethylene-polyoxypropylene in Claim 1 and replacement of the generic product in lieu of Carbopol in Claim 15 is found in the specification on page 4, lines 30-31 and page 5, lines 26-28, respectively. Since the amendment should address the Examiner's concerns, it is respectfully asked that this rejection be withdrawn.

If any outstanding issue remains in this case, the Examiner is invited to contact the undersigned attorney to discuss mutually agreeable solutions.

Accordingly, it is believed that this application is now in condition for an allowance. Favorable treatment is respectfully urged.

Respectfully submitted,

WYETH

Date: December 7, 2005

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